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Application No. 10/527,727

REMARKS

This Amendment is responsive to the Office Action mailed December 11, 2006 (hereinafter "Office Action"). By this Amendment, claims 1, 5, 7-9, 11-12, 14, 17 & 20 are amended. No new matter is added.

Claim Rejections - 35 U.S.C. § 112, second paragraph

In the Office Action, claims 1-20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants believe that the current claim amendments overcome this rejection. No new matter is added. Applicants respectfully request withdrawal of these rejections.

Claim Rejections - 35 U.S.C. § 103(a)

In the Office Action, claims 1, 5-6, 11-12 and 18-19 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler") in view of U.S. Patent No. 6,200,603 issued to Rowe *et al.* (hereinafter "Rowe").

The Stapler reference neither discloses microcapsules with a coating, nor does it disclose the claimed plasticizer content of 10 – 30 % (m/m). According to the Examiner, this document nevertheless renders the subject matter of pending claim 1 obvious.

Applicants believe that the rejection is a result of inadmissible hindsight because Stapler is from a nonanalogous art and there would be no motivation to rely on Stapler to make the claimed coated microcapsule. A person of ordinary skill in the art would not have consulted documents relating to uncoated microcapsules when trying to develop a coated microcapsule. This is reinforced by the fact that the cited documents are drawn solely to uncoated microcapsules production or solely to coated microcapsule production. If methods for producing uncoated microcapsules were obviously adaptable for the production of coated microcapsules, then there would not be any need for patent literature in the field of the production of coated microcapsules. In fact, all of the documents relating to the production of coated microcapsules emphasize the special difficulties in the production of coated microcapsules. Clearly, there is no motivation to combine the Stapler disclosure with a

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reference dealing with coated microcapsules. Furthermore, because Stapler does not provide any hints for the production of coated microcapsules, Applicants believe that this document is merely general prior art that is not suitable for rendering the claimed invention obvious.

The Rowe reference discloses the production of coated, filled microcapsules with a coating of gelatine glycerine and sugar and a sugar replacement like sorbitol. The ratio between gelatine and plasticizer (glycerine + sugar/sugar replacement) is 0.7:1 to 1.2 : 1 and thus well outside that claimed in claim 1, which range from 9:1 to 3:1.

The Examiner argues that a person of ordinary skill in the art would nevertheless try to develop other mixtures of gelatine and plasticizer, as Rowe indicates a correspondence between softness and flexibility of the microcapsule coating on the one hand and the gelatine and plasticizer content on the other hand. However, this argument simply ignores the fact that the variables cited in the Office Action were not recognized as results determinative for the relevant property: reducing stickiness. It was not the problem of the present invention to "somehow" influence softness or flexibility of a microcapsule coating. Instead, the present invention endeavored to provide microcapsules that do not stick to the teeth, tongue, gums or palate, *see* Specification, paragraph [0020]. There is nothing in the cited references that discloses or suggests that softness or flexibility of a microcapsule coating could be relevant for solving the problem of the unpleasant haptic effect, a comparatively long residence time in the oral cavity, and stickiness, *see* Specification, paragraph [0015]. The person of ordinary skill in the art would not have modified the rheological properties of the microcapsule's internal shell material. Rather, a skilled person would have tried to modify the tackiness properties by adjusting the properties of the of the microcapsule's outer coating. It is clear that a skilled person would have attempted to solve the relevant problem of the present invention by addressing the outer coating because the microcapsule coating is the part of a microcapsule that comes into contact with teeth and tongue etc. so it would be expected that the outer coating and not the internal shell would drive the stickiness properties of coated microcapsules.

Even if, *arguendo*, a skilled person would have contemplated to adjust plasticizer to gelatine ratios undisclosed in the Rowe reference, the ratio of pending claim 1 would nevertheless not have been obvious. The Rowe reference specifically instructs to *decrease* the gelatine content, *see* Rowe, column 2, lines 25 to 39 and 49 to 53). The skilled person thus had

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no reason to contemplate increasing gelatine content as claimed in pending claim 1. The Rowe reference clearly teaches away from the claimed combination. Thus, the claimed invention would require the skilled person to actively disregard the clear instructions of Rowe.

The Examiner also combines the Rowe and Stapler references, indicating that Rowe instructs the use of a minimum of shell material. However, the disclosures of the references must be considered as a whole to determine whether such a combination is suggested. Applicants assert that when taken as a whole, there is no motivation to combine the references as set forth in the claimed invention. Finally, the properties allegedly possessed by Rowe in the last paragraph of page 6 of the Office Action are not from Rowe (it appears they may be from Matthews). Thus, the cited references fail to establish a *prima facie* case of obviousness. For at least these reasons, Applicants believe that the current claims are distinguishable over the cited references.

In the Office Action, claims 2-4, 7-10, 13-17 & 20 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler") in view of U.S. Patent No. 6,200,603 issued to Rowe *et al.* (hereinafter "Rowe") in view of some combination of U.S. Patent No. 4,816,259 issued to Matthews *et al.* (hereinafter "Matthews"), U.S. Patent No. 6,770,311 issued to Alamian *et al.* (hereinafter "Alamian"), U.S. Patent No. 5,378,131 issued to Greenberg *et al.* (hereinafter "Greenberg"), U.S. Patent No. 5,342,626 issued to Winston, Jr., *et al.* (hereinafter "Winston") and U.S. Patent No. 4,888,140 issued to Schlameus *et al.* (hereinafter "Schlameus"). Applicants now address these references.

Matthews discloses gelatine microcapsules with a gelatine content of 70 % (m/m) and multiple coating layers. However, Matthews also describes that the microcapsule shell composition is specifically adapted to the composition of the "subcoating" also disclosed in Matthews. Applicants note that Matthews does not describe or suggest any alternative shell compositions. Thus, for an skilled person not relying on hindsight, Matthews would have only disclosed that a shell material composition has to be maintained when used in combination with a specific "subcoating." Thus, Matthews does not lead the skilled person to making the present invention.

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Further, if the skilled person would have tried to produce hard gelatine microcapsules based on the Matthews reference they would have been instructed by this reference to increase the sugar content of the shell material. Thus, it would not have been obvious to provide a high gelatine content or increase the gelatine content. Furthermore, the skilled person would not have had any chance to further contemplate the specific sizes mentioned in claim 1 of the pending application. And indeed the special difficulties in producing thin-walled microcapsules described on pages 8 and 9 of the present application would have deterred the skilled person from testing these dimensions. Thus, the skilled person would not have contemplated the subject matter of pending claim 1 when considering the Matthews reference.

According to the Examiner, Alamian discloses that a skilled person would contemplate the use of gelatine, fish gelatine etc. and alginate for the production of microcapsules. However, the capsules described by Alamian are explicitly said to be caviar replacements. It is well-known that caviar is sticky. Thus, when trying to produce non-sticky microcapsules, the skilled person would not have contemplated the use of the materials mentioned in the Alamian reference since he would have to believe that these materials would render the microcapsules sticking to teeth, tongue etc.

The Examiner cites Greenberg to establish that the skilled person would have contemplated using the flavours mentioned in pending claims 10 and 14 in the production of microcapsules. This document is simply not relevant because it does not effect novelty and inventiveness of pending claim 1.

Winston describes compositions for capsules and encapsulation processes. However, Winston does not disclose that the materials would be any useful in the production of microcapsules. Thus, we believe the document is not relevant for assessing novelty and inventiveness of the present invention.

Schlameus discloses a method for producing round, filled microcapsules. However, Schlameus does not disclose providing a coating on the microcapsules. In addition, Schlameus does not provide any indication regarding the stickiness properties of the microcapsules. It is thus our impression that the document is just general prior art and not any relevant for assessing novelty or inventiveness of the present set of claims.

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For at least the above reasons, Applicants believe that claim 1 is drawn to allowable subject matter. Applicants also believe that the dependent claims are drawn to allowable subject matter due to their dependence on claim 1 and the additional limitations recited therein. Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to issuance of the patent, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Applicants hereby authorize the Commissioner to charge the \$450.00 fee for a retroactive two month extension of time to Deposit Account No. 50-0951. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 50-0951.

Respectfully submitted,

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Stephan A. Pendorf
Registration No. 32,665
Gregory M. Lefkowitz
Registration No. 56,216
AKERMAN SENTERFITT
222 Lakeview Avenue, Suite 400
West Palm Beach, FL 33401-6183
Tel: (561) 653-5000
Fax: (561) 659-6313